### **Global Quality Management Advisors**



# ~ Quality ~

# What Is It ~ What It Is

# ~ What's The Problem ~

White Paper

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#### **Abstract**

In this paper, I share 50 years of working knowledge performing in high-consequence heavily regulated business sectors (mostly startups) regarding 'The Management of Quality.' Considerable content is from the GQM Advisors white paper of September 2024, (P.W. Gladieux & S.B. Kaley), Your C-Suite & CQO, 'Is There One Common Sense Reason to Keep a CQO Out of Your C-Suite'?¹ My insights are from extensive experience in management systems engaging in Nuclear Energy Operations (7 years, 4 power reactors ~ Entergy Operations), Supply Chain Services (more than 30 suppliers), Reactor Design Suppliers (Westinghouse Nuclear, NuScale Power, TerraPower, BWX Technologies), Large Scope Design/Build Programs (Jacobs Engineering Group, 5 years), Custom Engineered Products (12 years). These engagements were in complex management systems in high-risk/high-value sectors. I explore and pose questions regarding the critical role of 'The Management of Quality' and attempt to clarify the word 'Quality' and the role of the 'Quality Discipline' in business operations and programs. I will consider this paper a success, if it helps one or some organizations establish their basis for adopting a definition of Quality and gaining Quality Performance Improvements in Practice.

#### What is Quality? ~ The Never-Ending Question

Isn't quality a simple understanding of what you like and dislike or what works and doesn't work? Isn't it shopping and finding a sweater that fits perfectly, compliments your wardrobe, and helps you feel good? Isn't it having your favorite food on a Saturday evening with your favorite friends? If your friends pick up the tab, perhaps you've experienced 'total satisfaction.' Perhaps it's having your favorite cake with family members on your birthday. We know what it is when it comes to our personal quality of life.

Come Monday morning, we're on our way to work to make a living and contribute to the goals and objectives of a business enterprise. Isn't it true you enter an environment of requirements that must be met to achieve specified results? Are you showing up for what will be a great week or, will your week start with numerous unknowns: nagging unsolved supplier problems, needing to wear three hats because of an operational RIF two weeks ago, trying to influence the lead design engineer on your proposed solutions, or overly concerned about the procurement group always being behind schedule with a compliance audit beginning in two days. Every week, we face another week of meeting quality requirements in our work life.

IN THE MEDIEVAL GUILDS OF EUROPE<sup>2</sup> ~ The quality movement can trace its roots back to medieval Europe, where craftsmen began organizing into unions called guilds in the late 13th century. These guilds were responsible for developing strict rules for product and service quality. Inspection committees enforced the rules by marking flawless goods with a special mark or symbol.



Craftsmen themselves often placed a second mark on the goods they produced. At first this mark was used to track the origin of faulty items. But over time the mark came to represent a craftsman's good reputation. Inspection marks and master craftsmen marks served as proof of quality for customers throughout medieval Europe. This approach to manufacturing quality was dominant until the Industrial Revolution in the early 19th century.

IN THE INDUSTRIAL REVOLUTION<sup>2</sup> ~ Until the early 19th century, manufacturing in the industrialized world tended to follow this craftsmanship model. The factory system, with its emphasis on product inspection, started in Great Britain in the mid-1750s and grew into the Industrial Revolution in the early 1800s. American quality practices evolved in the 1800s as they were shaped by changes in predominant production methods.

IN MODERN TIMES DEFINITIONS EMERGED ~ There are several quality definitions, some industry-specific, that have emerged over the past 10 decades. The most important aspect is that each person understands the applicable definition used by their employer or customer and continually pursues improvements and excellence in what work they perform. The world has improved in endless ways because of the pursuit of quality improvement. Definitions have emerged over time. There are probably others.

- For starters, quality can be represented by how time and energy is being used to accomplish tasks
- A degree of excellence
- fitness for intended use
- Conformance to requirements
- Superiority in kind
- Customer satisfaction
- Fitness for use
- Doing things right the first time
- Zero defects
- It can represent how many ISO9001 requirements are met
- The degree to which an item or process meets or exceeds the user's requirements and expectations

IN TODAY'S GLOBAL HIGH TECHNOLOGY ERA<sup>3</sup> ~ The American Society for Quality (ASQ) addresses Quality 4.0. Digital Transformation Technological advances of the past decade have resulted in a new industrial revolution often referred to as the fourth industrial revolution or "Industry 4.0." It's a revolution driven by the exponential growth of disruptive technologies and the changes those technologies are bringing to the workplace, the workforce, and the markets organizations serve. https://asq.org/quality-resources/quality-4-0



"Quality 4.0" is a term that references the future of quality and organizational excellence within the context of Industry 4.0 needs and performance expectations. Quality professionals can play a vital role in leading their organizations to apply proven quality disciplines to new, digital, and disruptive technologies.

#### IN TODAY'S GLOBAL MOVEMENT ~ FOR 'THE MANAGEMENT OF QUALITY'

The ongoing efforts to demystify quality and establish a consensus on its context include entities such as:

- U.S. American Society for Quality, Excellence Through Quality, Excellence Through Quality | ASQ
- ISO 9001 QMS Standards, Concept and Definition of Quality, ISO 9001 Clause 3: Terms and Definitions (iso-9001-checklist.co.uk)
- Merriam-Webster, QUALITY Synonyms: 271 Similar and Opposite Words | Merriam-Webster Thesaurus
- U.S. Home: The Foundation for the Malcolm Baldrige National Quality Award (baldrigefoundation.org)
- U.S. NIST Quality System | NIST
- U.S. The W. Edwards Deming Institute
- U.S. Quality Leadership & Operational Excellence Juran
- U.S. Department of The Navy <u>U.S.-Dept-Of-The-Navy-TQL-In-The-Fleet-Theory-to-Practice-J.Wasik-B.Ryan-1993-AD-A275-444-92pgs.pdf (gqmadvisors.com)</u>

IN PRACTICE<sup>4</sup> ~ The profession encompasses Four Management Disciplines, <a href="https://gqmadvisors.com/disciplines/">https://gqmadvisors.com/disciplines/</a>

- Quality Leadership (QL) The Department of the Navy's definition of QL is based on W. Edwards Deming's ideas. "The application of quantitative methods and the knowledge of people to assess and improve a) materials and services supplied to the organization, b) all significant processes within the organization, and c) meeting the needs of the end-user, now and in the future." U.S. Depart of The Navy TQL In The Fleet Theory to Practice, J. Wasik, B. Ryan, 1993, AD-A275 444, 92pgs.
- Quality Management (QM) That aspect of the overall management function that determines and implements quality policy.
   Quality management includes strategic planning, allocation of resources, and systematic activities for quality such as quality planning, operations, oversight, and evaluation.
- Quality Assurance (QA) Those planned and systematic activities implemented within the quality system that can be
  demonstrated to provide confidence that a product or service will fulfill requirements for quality.
- Quality Control (QC) Those actions that provide a means of control and measure of the characteristics of an item, process, or facility to established requirements (inspection or source surveillance, or both).
- Quality's Path to Leadership ~ Timeline QC | QA | QM | QL CQO (See last page)<sup>5</sup>
   https://gqmadvisors.com/wp-content/uploads/2024/06/GQMadvisors-1900-2024-Tmln-QC-QA-QM-QL-CQO-06-10-24-R1-1sld-1.pdf

IN BUSINESS ~ The Quality word is used in numerous ways as a noun and adjective such as: Quality Policy, Quality Plan, Quality Management, Quality Assurance, Quality Control, Quality System, Quality Management System, Quality Tools, Quality Culture, Quality Program, Quality Inspection, Quality Test, Quality Engineering, Quality Audit, Quality Assessment, Quality Nonconformance (and Noncompliance), Quality Corrective Action, and Quality Report.



IN ROLES AND RESPONSIBILITIES ~ If you search job boards, you'll find numerous position descriptions encompassing over 100 areas of responsibility ~ Why? Some position description job postings include well over 35 'bullets' of responsibilities. Likely you won't find postings for CPAs, Engineers, Contract Managers, Attorney's, HR Managers, and others with long bulleted lists of responsibilities because people generally understand what work they perform. That tells us that employers do not understand and don't properly apply the Four Quality Disciplines within their organizational structure. 'Quality Managers' don't manage quality; they assist with the management of quality. Quality Managers and Quality Directors perform responsibilities that assist and advise the workforce. Many in the workforce still fear those working in the quality organization ~ Why?

#### Quality Gurus ~ Philosophies, Schools of Thought, Applications<sup>6</sup>

The industrial revolution is nearing a 125-year milestone. The advances for humankind are remarkable with incredible life extension and Quality of Life improvements. Global Quality Thought Leaders have dedicated their lives to sharing insights in both philosophical and application aspects. The one common characteristic pertaining to quality we all understand is people. Without commitment, trust, desire, teamwork, and ownership for the quality of one's own work, no entity will survive and achieve excellence. Several individuals are known for their leadership in the management of quality. The ASQ website is a nice location to visit for information regarding the work and studies by: Juran, Taguchi, Garvin, Crosby, Shingo, Deming, Feigenbaum, and Ishikawa.

https://asq.org/quality-progress/articles/guru-guide?id=851d6f00e23044a58006d04e0df2df33

Deming's Philosophy, known as Dr. Deming's "theory of management" and later his "System of Profound Knowledge," represents a comprehensive approach to leadership and management. His philosophy brings together an understanding of variation, theory of knowledge, psychology, and appreciation for a system.

A Philosophy of Quality

Dr. W. Edwards Deming's outlook on quality was simple but radical. He asserted that organizations that focused on improving quality would automatically reduce costs while those that focused on reducing cost would automatically reduce quality and actually increase costs as a result.



Crosby's Philosophy is known for the Four Absolutes of Quality: 1 - The definition of quality is conformance to requirements. 2 - The system of quality is prevention. 3 - The performance standard is zero defects (ZD). 4 - The measurement of quality is the price of non-conformance. In the 1980s, ZD met with push back because of the inference that companies can routinely produce 'perfect' product every time. Unfortunately, Crosby's ZD was merely a philosophical target to always stretch to achieve zero defects.



#### **Quality Guru Quotes**<sup>7</sup>

- "Quality is free. It's not a gift, but it's free. The unquality things are what cost money." Philip Crosby
- "If you can't describe what you are doing as a process, you don't know what you're doing." W. Edwards Deming
- "Quality improvement at a revolutionary pace is now becoming simply good management." A. Blanton Godfrey
- "Quality control is applicable to any kind of enterprise; in fact, it must be applied to every enterprise." Kaoru Ishikawa
- "As is the case in everything we do, unknown or chance causes exert their influence." Walter A. Shewhart https://asq.org/quality-resources

Here is another source for understanding the teachings, methods, and philosophies of some Quality Gurus 'QG'8 <a href="https://www.qualitygurus.com/9-quality-gurus-and-their-contributions/">https://www.qualitygurus.com/9-quality-gurus-and-their-contributions/</a>

#### **Quality Management Tools<sup>9</sup>**

Seasoned quality management professionals are aware of and use the various quality tools throughout their business operations. Obviously, the key to success is to use the most effective tool(s) that correlate to the work application(s).

• Fishbone Diagrams

• Design of Experiments (DOE)

• Quality Plans

• Gantt Charts

• Scatter Diagrams

• Value Stream Mapping

Pareto Charts

• Requirements Management Matrix (RMM)

• Impact Effort Matrix

Benchmarking

• Quality Function Deployment (QFD)

• Statistical Controls

https://asq.org/quality-resources/quality-tools

Now Artificial Intelligence (AI) presents considerations and understanding as executives review their business strategies for this wave of change. The AI movement will surely cause the workforce to adapt, engage in continuous learning and training, seek career changes, manage new approaches to work, and leverage the capabilities for improvements in quality, safety, cost, schedule, and security.

If defining and implementing the management of quality as a key management discipline is simple, why has it taken over 100 years to essentially crystalize the few definitions of quality and have a logical basis for execution across numerous global sectors? Consistent use of the quality language is critical for communicating quality-related requirements, activities, and tasks. According to Census Bureau Statistics of U.S. Businesses<sup>10</sup> there were over 30 million businesses in 2023 <a href="https://www.census.gov/programs-surveys/susb.html">https://www.census.gov/programs-surveys/susb.html</a> Is everyone using the same terms and definitions?

As of April 2024, over 20,000 U.S. companies were ISO9001 Quality Management System certified. Considering there's 30 million companies, why are so few QMS certified? The ISO quality standards are not that difficult to achieve certification or just compliance. The formal quality movement is clearly a work in-progress since the family of quality management standards were published for implementation in 1987.



#### **Quality Glossary ~ Learn the Language**

The concepts of Quality include their own language just like finance, engineering, program management, safety, automation, cybersecurity, and other management disciplines have their unique terms and definitions. Our online search for quality synonyms resulted in more than 90 terms in Merrian-Webster. The ASQ<sup>12</sup> is an excellent source for terms and definitions: <a href="https://asq.org/quality-resources/quality-glossary">https://asq.org/quality-resources/quality-glossary</a> Professional societies and industry entities typically have their own glossaries.

#### **Quality ~ Defined Performance Requirements vs. Perception**

The workforce knows their job is to perform to the standards set by their leaders. It's our desire that you have a strong understanding of your own philosophy and perception of quality and how it applies to your principles and practices in your organization. We expressed how the concept is seemingly simple, until faced with certain situations, especially in a complex work environment. Most individuals in the workplace know that it doesn't take much of a quality problem to tarnish a company's reputation.

One of the roles of the quality professional is to assist the organization with defining performance metrics and determining the proper methods for measuring and verifying conformance to requirements in customer contracts and engineering specifications. Quality engineers typically focus on assisting the workforce for engineered products and services.

#### What are Requirements?

Basic teachings on quality are founded on the value that if all <u>requirements</u> for procuring something (product or service) are clear, accurate, and achievable (supplier capability), then it's a matter of accepting or rejecting what is produced and delivered. If contract terms, conditions, and specifications have been met, and you are a 'satisfied customer,' then quality has been achieved.



Seasoned quality management professionals know their job is to advise and assist C-Suite executives, senior management, and the workforce in deploying quality-related policies, process descriptions, and procedures that are customer contract-based. The deployment goal is an effective management system within legal frameworks and proven quality system structures based on international norms, regulatory requirements, customer contracts, and corporate objectives. They know each person is responsible for the quality of their work activities and tasks related to stated deliverables.



I believe a simple and effective definition of quality that most people can relate to is 'Conformance to Requirements.' This definition was established by Dr. Philip B. Crosby in his 1979 ground-breaking book 'Quality is Free'<sup>13</sup> ~ The Art of Making Quality Certain – How to Manage Quality so that it becomes a Source of Profit for Your Business. I believe that was a bold position to take in 1979 ~ how could quality be free?



Dr. Crosby defined a simple approach and perspective by posing the idea of quantifying the number of requirements in his short article 'What are Requirements' published in Quality Progress 1987. In it, he uses an example of one million requirements to run an operation vs. how many requirements were met. Some organizations use Requirements Management Software to account for quality and safety requirements. I'm sure readers would agree that it only takes one 'nonconforming requirement' to devastate an enterprise or one's personal life.

Seasoned quality management professionals know they are performing in an environment with complex legal implications. Those in high-consequence sectors such as aviation, aerospace, healthcare, nuclear energy, military asset suppliers are dealing with hundreds of thousands of requirements, if not millions, with critical safety implications. We need to ask routinely if quality-related and safety-related requirements are correct and met every time. A Risk Management (Threat and Error Management) 'What If' workforce environment is imperative. One thought to employ is to use a 'peer review,' 'do-verify list,' or 'self-assess,' discipline for your own work. Perhaps ask a fellow worker for an informal peer review.

What's fascinating about the word quality and its use, is everyone has their own interpretation of what quality is. One challenging aspect is perception. After numerous books, thousands of articles, many certification programs, and many online training courses, wouldn't you think Quality is finally accepted as a critical management discipline with routine understandings, one definition, and in C-Suite's via a Chief Quality Officer (CQO)?

In business we measure quality and produce quality metric charts and reports for making high consequence-related decisions. Most people in the workforce know that quality may have severe direct and indirect outcomes and legal implications. My experience reveals that the usage and meaning of Quality are the same across 85% of the organizations systems, programs, processes, and procedures. I believe having a CQO in the C-Suite would assist the executive team in defining an organization's quality-related goals and objectives, and further demonstrate their commitments.



#### Reason is the Soul of Law<sup>15</sup>

Thomas Aquinas' definition of law is very brief and straight-forward. Most lawyers and even college students will at least have heard of it. It reads: "Law is an ordination of reason, by the proper authority, for the common good, and promulgated." Many things are stated and implied in this brief, compact sentence.



Product and service law essentially touches all our lives. The USA is known as the most litigious society in the world. Products have extensive statements on labels. Credit cards are ladened with

legalese wording. Candy bar wrappers include quality policy statements. Warranty labels seem to be everywhere.

Typically, we want to be protected by the law and not be a victim of it. Quality professionals know part of their expertise must be a fundamental understanding of the law and its implications. Before placement of a purchase order, or when a concern arises and a quality professional states "I need to read the contract and specifications," aren't they protecting the company and the public?

#### Quality and The Law ~ Ignorance of the Law Excuses No One

In my contract roles, I knew the inherent need for understanding Quality and The Law. I've always endorsed and lived by the saying 'Ignorance of the Law Excuses No One' knowing that principle is integrated in the safety and quality cultures. My daily work was performed in environments of federal codes, industry standards, contract terms and conditions, performance specifications, and complex contract deliverables ~ the real world of Quality and the Law.



#### **Quality** ~ Assessments | Audits | Surveillance

Assessments, audits, and surveillance are used to determine a level of conformance to requirements. On occasion, they reveal when the product or service exceeds expectations. Each tool has its own purpose, approach, execution methods, and results. The common thread is to produce performance metrics for executives and line management in a way that focuses on potential process improvement of products and services. It's critical to ensure that individuals performing in these roles are qualified and certified when required. The preparation step must be performed using the applicable requirements in contracts, specifications, process descriptions, and process-related documents. Highly skilled individuals typically perform in these roles with minimum impact on operations and promote a spirit of esprit de corps and leaving workers with a positive experience. The goal is always centered on identifying current and potential issues resulting in improvement.

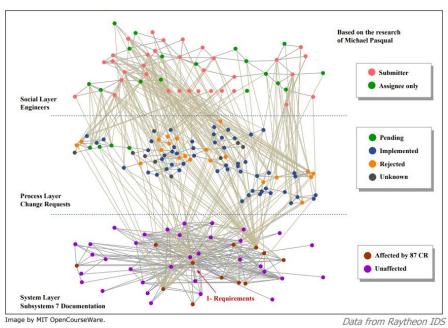


#### **Quality Performance Metrics ~ Requirements | Data Management**

The advent of product final test and inspection and then soon following with statistical process control in the early 1900s, paved the way for business owners and executives to know the levels of consistency of their products and services. Without these advancements supporting mass production of goods required for the WWII effort, historians know the outcome would have been different. In modern times we can benefit from two added business disciplines: Requirements Management (RM) and Data Management.

The RM model by MIT Open CourseWare, based on research by Michael Pasqual, (Data from Raytheon IDS), provides an impactful image of the complexities of requirements within a management system architecture.





Seasoned quality management professionals think in terms of the geometric progression of a requirement and typically visualize their paths among functional disciplines. CQOs typically reveal quality performance in terms that will be shared with C-Suite executives. The CQO, CFO, and COO can express operational performance in terms of Cost of Quality vs. Cost of Poor Quality. Executives will understand profit relative to quality levels of effort.

From those early years of data gathering based on specified core and project requirements, companies have gained vast market shares and greatly enhanced quality performance. Examples of RM | DM software platforms include:

- Jama Software https://www.jamasoftware.com/
- IBM https://www.ibm.com/topics/what-is-requirements-management
- Perforce <a href="https://www.perforce.com/products/helix-requirements-management">https://www.perforce.com/products/helix-requirements-management</a>
- RegSuite RegSuite® RM Reviews 2024: Details, Pricing, & Features | G2



#### **Quality Professionals**

I know from my relationships with member Executive Advisors in our Group; that other sectors, segments, and applications are faced with the same and many similar regulatory, industry, business, and customer compliance requirements e.g., healthcare, medical device manufacturing, pharmaceuticals, military asset suppliers, ship and bridge building, government site management, engineered safety systems suppliers, and design/build contractors. 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> tier suppliers produce the same or similar products and provide services across multiple sectors and segments. Many of the suppliers are faced with being qualified or certified, which typically results in suppliers using the Requirements Management Matrix quality management tool for ensuring accuracy and compliance.

A fundamental principle supporting the management of quality in our modern times, especially in regulated sectors, is that quality professionals are 'free from production pressure.' This does not mean they have the right to slow or stop production unless there is good reason(s). In our past work environments, anything known or 'suspected' is just reason(s) to slow or stop work. In nuclear power generation and aviation, essentially everything is considered 'safety-related.' Our daily routines included always thinking (situational awareness) and 'sweeping areas' (observation) for possible quality problems.

#### The Federal Department of Quality (DOQ) ~ U.S. Secretary of Quality

Please think about it. Doesn't it make common sense to have a Federal Department of Quality headed by a Secretary of Quality? We have the DOJ, FBI, DOE, EPA, FAA, OSHA, DOC, NRC, DHS, and others. Why not the U.S. DOQ? A starting point is a commitment by the executive branch and congress to enact the U.S. Malcolm Baldrige Performance Excellence Program<sup>16</sup> throughout all U.S. federal governmental organizations. Considering the global adoption and implementation of the International Organization of Standards for quality, safety, environmental, aviation, medical, cybersecurity, and other management system disciplines; I believe certain requirements in these documents should also be committed to by applicable government entities.

#### **Conclusion**

Conforming to Requirements is a simple concept and something everyone should understand whether at work, home, school, church, travelling, medical care, and the communities and neighborhoods around the world. What most would call 'Quality of Life.' I will continue efforts to bring general issues of Quality Awareness to everyone.

I will consider this paper a success, if it helps one or some organizations establish their basis for adopting a definition of Quality and gaining Quality Performance Improvements in Practice.



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